K002931

NOV 2 4 2000

510(k) Summary
METRx Microscope and Accessories
September 2000

I. **Company:** Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38120
901-396-3133
Richard W. Treharne, Ph.D.

II. **Product Trade Name:** METRx™ System
Common or usual name: Microscope
Classification name: Microscope and Accessories (FSO and EPT as described in 21 CFR 878.4700)

III. **The labeled indications for use for the METRx™ System are as follows:**

The METRx™ Microscope is indicated for visualization of the surgical field in any area of the body cut open during a surgical procedure. When used in the cervial, thoracic, or lumbar spine either from an anterior or posterior direction, for example, the METRx Microscope and accessories are intended to aid the surgeon's visualization of the surgical area and allow him/her to perform any type of surgical spinal procedure such as herniated disc repair, visualization of the circumferential decompression of the nerve roots, aiding in the search and removal of nucleus material, spinal fusion, or insertion of spinal implants. Other examples of generic surgical use of the METRx Microscope would be for use in the knee, ankle, shoulder, hand, wrist, and temporomandibular joint (TMJ).

VI. The technological characteristics of the device were claimed be the same as or substantially equivalent to those of predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2000

Richard W. Treharne, Ph.D.
Senior Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K002931
Trade Name: METRx™ System
Regulatory Class: II
Product Code: HRX
Dated: September 18, 2000
Received: September 20, 2000

Dear Dr. Treharne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002931

Device Name: METRx™ Microscope – Indications Modification

Indications For Use:

The METRx™ Microscope is indicated for visualization of the surgical field in any area of the body cut open during a surgical procedure. When used in the cervial, thoracic, or lumbar spine either from an anterior or posterior direction, for example, the METRx Microscope and accessories are intended to aid the surgeon's visualization of the surgical area and allow him/her to perform any type of surgical spinal procedure such as herniated disc repair, visualization of the circumferential decompression of the nerve roots, aiding in the search and removal of nucleus material, spinal fusion, or insertion of spinal implants. Other examples of generic surgical use of the METRx Microscope would be for use in the knee, ankle, shoulder, hand, wrist, and temporomandibular joint (TMJ).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K002931